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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,409	07/15/2004	Kenji Okada	YMOR:330	9556
27890	7590	01/25/2008		
STEPTOE & JOHNSON LLP 1330 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036			EXAMINER RAMILLANO, LORE JANET	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 01/25/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,409	Applicant(s) OKADA ET AL.	
	Examiner Lore Ramillano	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7-13 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,7-13 and 16-18 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/15/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/31/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

Status of Claims

2. In applicant's reply filed on 10/31/07, applicant amended claims 1, 7-11, 13, 16, and 18; cancelled claims 2-4, 6, 14-15, and 19. Claims 1, 5, 7-13, and 16-18 are pending and under examination in the application.

Claim Objections

3. In light of applicant's new amendments, a new objection follows.
4. Claim 5 is objected to because of the following informalities: the claim from which it depends on is cancelled. Appropriate correction is required.

For examination purposes, examiner will interpret claim 5 to depend on claim 1.

Claim Rejections - 35 USC § 112

5. The rejection of claim 18 under 35 U.S.C. 112, second paragraph, is withdrawn. In light of applicant's new claims, new rejections follow.
6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 5, 7-12, and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because the language, "recessed into a rear surface of the upper substrate" does not appear to distinctly claim the subject matter of applicant's invention. Is applicant intending to describe the location of the channels in the upper substrate?

Claim 1 is rejected because the recited, "first hole" and "second hole," do not appear to distinctly claim the subject matter of applicant's invention. Based on the disclosure, it appears that applicant's invention has one axial in the center of the upper and lower substrate. Is applicant intending to claim that the "axial hole" is made of a first hole and a second hole?

Prior art rejections

8. In light of applicant's amendments, the rejections over the prior art are withdrawn. New rejections follow.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. **Claims 1, 5, 7, 8, 10, 13, and 16-18** are rejected under 35 U.S.C. 102(b) as being anticipated by Takase et al. ("Takase," EPO 0 417 305 A1).

Takase discloses a disk-shaped upper substrate having a first hole through a center thereof, the upper substrate (i.e. 101a, fig. 8(b)) comprising:

a plurality of injection ports (105) cut through the upper substrate and located around the first hole in circumferentially spaced relation to each other;

plurality of water absorbing members recessed into a rear surface of the upper substrate and in a radially outer peripheral portion of the disk in circumferentially spaced relation, each of the water absorbing members comprising a porous material and containing a blood coagulating agent for coagulating a liquid specimen (i.e. col. 15, lines 4-13);

a plurality of channels recessed into a rear surface of the upper substrate, each of the channels connecting an injection port to a water absorbing member, and extending radially straight from the injection port to the water absorbing member, each of the plurality of channels comprising: a plurality of analysis areas, each located midway in a channel and coated with a reagent for reaction with a constituent of a liquid specimen to be analyzed (i.e. col. 5-6; col. 15, lines 4-13); and

a lower substrate bonded with a second hole at a center thereof, the lower substrate bonded to the upper substrate, and comprising: a reflective film on a surface of the lower substrate (i.e. col. 12, lines 43-51),

wherein the analysis disk is rotatable about an axis thereof to pass a liquid specimen injected into a channel from an injection port to an analysis area and a water absorbing member. (i.e. col. 4).

Takase further discloses the following: an outer end portion of the channel provided with the water absorbing member has a greater width than a portion of the channel radially inward of the outer end portion (i.e. fig. 2(d)); a portion of the channel radially inward of an outer end portion provided with the water absorbing member is bottlenecked (i.e. fig. 2(d)); a portion of the channel which is radially inward of an outer end portion provided with the water absorbing member is coated with a hydrophobic material (i.e. polystyrene); optical detection means which scans the analysis area to optically detect a constituent of the liquid specimen guided through the channel toward the outer periphery of the disk by the rotation (i.e. col. 8-12); the plurality of channels are placed equidistantly from each other (i.e. fig. 2(a)); the outer end portion of the channel is adjacent to a terminal end of the channel, and the terminal end of the channel is positioned opposite to the injection port (i.e. figs. 2-5); and the water absorbing member at a terminal end of the channel is for absorbing a liquid specimen (i.e. col. 15, lines 4-13).

11. **Claims 1, 5, 7, 9, 10, 13, and 16-18** are rejected under 35 U.S.C. 102(e) as being anticipated by Krutzik et al. ("Krutzik," US 7141416).

Krutzik discloses a disk-shaped upper substrate having a first hole through a center thereof, the upper substrate comprising:

a plurality of injection ports (122) cut through the upper substrate and located around the first hole in circumferentially spaced relation to each other;

plurality of water absorbing members recessed into a rear surface of the upper substrate and in a radially outer peripheral portion of the disk in circumferentially spaced relation, each of the water absorbing members comprising a porous material and containing a blood coagulating agent for coagulating a liquid specimen (i.e. col. 12, lines 16-24);

a plurality of channels recessed into a rear surface of the upper substrate, each of the channels connecting an injection port to a water absorbing member, and extending radially straight from the injection port to the water absorbing member, each of the plurality of channels comprising: a plurality of analysis areas, each located midway in a channel and coated with a reagent for reaction with a constituent of a liquid specimen to be analyzed (i.e. figs. 13-15); and

a lower substrate bonded with a second hole at a center thereof, the lower substrate bonded to the upper substrate, and comprising: a reflective film on a surface of the lower substrate (i.e. col. 12, lines 41-60),

wherein the analysis disk is rotatable about an axis thereof to pass a liquid specimen injected into a channel from an injection port to an analysis area and a water absorbing member. (i.e. col. 13, lines 35-52).

Krutzik further discloses the following: the plurality of channels are connected to each other at an outer end portions thereof (i.e. fig. 13); a portion of the channel which is radially inward of an outer end portion provided with the water absorbing member is coated with a hydrophobic material (i.e. col. 23, lines 12-45); optical detection means which scans the analysis area to optically detect a constituent of the liquid specimen guided through the channel toward the outer periphery of the disk by the rotation (i.e. fig. 20); the plurality of channels are placed equidistantly from each other (i.e. fig. 13-15); the outer end portion of the channel is adjacent to a terminal end of the channel, and the terminal end of the channel is positioned opposite to the injection port (i.e. figs. 13-15); and the water absorbing member at a terminal end of the channel is for absorbing a liquid specimen (i.e. figs. 13-15).

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Krutzik.

The disclosure of Krutzik is disclosed above. Krutzik does not specifically disclose having an outer end portion that has a greater width than a portion of the channel radially inward of the outer end portion.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Krutzik by having an outer end portion that has a greater width than a portion of the channel radially inward of the outer end portion because it would be desirable to provide a chamber for overflow.

14. **Claims 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Krutzik in view of Valencia et al. ("Valencia," US Pub. No. 2003/0219713).

The disclosure of Krutzik is disclosed above. Krutzik does not specifically disclose having a valve.

Valencia discloses an optical bio-disc comprising: a channel (i.e. 128, Fig. 4), which extends from an injection port (i.e. 122, Fig. 3D) toward an outer periphery and rotatable about an axis to cause a liquid specimen injected into the channel from the injection port to flow through an analysis area (i.e. 140, Fig. 4) located midway in the channel to a radially outer end portion of the channel. Valencia further discloses an optical bio-disc, which comprises a valve (i.e. 310) that regulates the flow of the sample through the channels ([0313]).

Krutzik and Valencia are analogous art because they are from the same field of endeavor, biological assays and diagnostic assays and, in particular, to such assays conducted on optical bio-discs. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Krutzik with the valve limitation of Valencia as stated above, because it would be desirable to have a structural means to regulate the flow of the sample through the channels.

Response to Arguments

15. Applicant's arguments, filed on 10/31/07 with respect to the rejection(s) under Werner and Braynin have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Krutzik and Takase.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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Lore Ramillano
Examiner
Art Unit 1797


Jill Warden
Supervisory Patent Examiner
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